

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

In re:	:	MDL No. 2419
	:	Docket No. 1:13-md-2419 (FDS)
NEW ENGLAND COMPOUNDING	:	
PHARMACY, INC. PRODUCTS	:	
LIABILITY LITIGATION	:	Judge F. Dennis Saylor, IV
	:	
THIS DOCUMENT RELATES TO:	:	
	:	
ALL ACTIONS	:	
_____	:	

**NONPARTY CENTENNIAL MEDICAL CENTER’S
RESPONSES AND OBJECTIONS TO
PLAINTIFF’S SUBPOENA TO TESTIFY AND PRODUCE DOCUMENTS**

Pursuant to Rules 26, 30, 34, and 45 of the Federal Rules of Civil Procedure, Non-Party Centennial Medical Center (“Centennial”), by its attorneys, Debevoise & Plimpton LLP, hereby responds and objects to Plaintiffs’ Steering Committee’s (“PSC” or “Plaintiffs”) Subpoena To Testify at A Deposition in a Civil Action, dated June 25, 2013 (the “Subpoena”).

Introductory Statement

Centennial seeks to comply with this Court's Order to provide Plaintiffs with relevant, non-privileged documents and information relating to the tainted NECC medications. However, the Subpoena is overly broad and unduly burdensome and seeks documents and testimony that are not at all relevant to the recalls of NECC tainted medications nor calculated to lead to the discovery of admissible evidence. Compliance with these requests would impose unwarranted burdens – in the form of expense, effort and time – on Centennial to locate and review documents that in most cases are irrelevant and immaterial to the facts at issue in the MDL litigation.

Centennial is not a party to the MDL litigation. It has not been named as a party in a single suit in the MDL litigation and, as far as Centennial is aware, not a single Centennial patient is a party in the MDL litigation. In fact, as far as Centennial is aware, not a single Centennial patient has filed suit in any forum in connection with the NECC fungal meningitis outbreak. Centennial did not order methylprednisolone acetate – the compounded medication that is believed to have caused the meningitis outbreak – from NECC. Nevertheless, the Subpoena compels Centennial to provide at least one corporate representative to testify under oath regarding 36 broad subjects and to produce 28 categories of documents. Specifically, the Subpoena calls for testimony on subject areas including:

- Centennial's creation, storage and organization of electronic and hard copy patient records and other documents;

- Centennial's procurement of six different types of compounded medications from New England Compounding Pharmacy and any other compounding pharmacy for a five year period;
- Centennial's practices and procedures regarding its selection of NECC and other compounding pharmacies;
- Centennial's use of NECC products or other compounded medications;
- Centennial's communications with NECC;
- Centennial's communications with federal and state regulators and law enforcement agencies;
- Centennial's insurance policies for the hospital and its officers and directors;
- Centennial's compliance with state laws and regulations;
- Centennial's corporate structure and ownership; and
- The identities of each and every patient, including their social security numbers and addresses, who received any NECC product.

The Subpoena further calls for the production of categories of documents including:

- All documents relating to the procurement of methylprednisolone acetate and any other injectable steroid from NECC or any compounding pharmacy for the five year period preceding the NECC recalls in October 2012;
- All documents relating to the procurement of three other types of medications from NECC for the five year period preceding the NECC recalls in October 2012;
- All documents reflecting the names, addresses and birth dates of all patients who received any medication from NECC for the five year period preceding the NECC recalls in October 2012;
- All documents pertaining to NECC's marketing and sales to Centennial;
- All documents relating to the September and October 2012 recalls of NECC products;

- All documents relating to Centennial's compliance with certain laws and regulations;
- All of Centennial's liability insurance policies for 2011, 2012, and 2013; and
- All documents reflecting Centennial's corporate structure, management, and ownership.

With very few exceptions, the Subpoena's requests are not remotely relevant to the claims at issue in the MDL nor are they calculated to lead to the discovery of admissible evidence in the MDL litigation. Instead, the Subpoena appears to be an improper fishing expedition to identify additional claims and clients for the Plaintiffs' counsel. Plaintiffs should not be permitted to use the power of this Court to impose these burdensome and impermissible requests on Centennial, which did not administer or even order any of the tainted methylprednisolone from NECC.

Objections to the Requests for the Production of Documents¹

Centennial objects to certain portions of Exhibit B to the Subpoena compelling the production of certain documents and materials. (The Subpoena, its Exhibits and accompanying correspondence are attached as Exhibit A).

¹ Nothing in Defendant's responses and objections herein shall be construed as a waiver of Defendant's rights to (i) object on the grounds of competency, relevance, materiality, hearsay or any other proper grounds to the use of any information provided in these responses for any purpose, in whole or in part, in any subsequent stage or proceeding in this or any other action; (ii) object on any and all grounds, at any time, during any discovery procedure relating to the subject matter of these documents; or (iii) assert the attorney-client privilege, the work product doctrine, doctor-patient privilege, or any other privilege or right.

1. Centennial objects to the portions of the Subpoena that seek the discovery of documents that are neither relevant to the issues raised in this action nor are reasonably calculated to lead to the discovery of evidence admissible in this action. Plaintiffs have failed to identify a single Centennial patient who has filed a claim or joined the MDL litigation. Centennial did not administer or even order any methylprednisolone from the NECC tainted lots and, as far as Centennial is aware, none of its patients have contracted fungal meningitis or suffered from other injuries in connection with the tainted NECC medications. Consequently, few if any of the documents that the Plaintiffs seek are relevant to the claims of any parties in the MDL litigations and Plaintiffs broad requests are not reasonably calculated to lead to the discovery of such evidence. Moreover, several of Plaintiffs' requests seek documents that do not involve NECC or the fungal meningitis outbreak at all. For example, Plaintiffs seek "any and all organizational charts" and "any documents listing directors, officers, employees, and/or agents of the Healthcare Provider showing the names and positions of said directors, officers, employees, and/or agents and their relationship or rank within the Healthcare Provider." They likewise seek Centennial's articles of incorporation and by-laws for the years 2011, 2012, and 2013.² Subpoena Ex. B Request Nos. 22 & 25. Centennial's organizational structure, leadership structure, and governance documents are not relevant to any of the claims at issue in the MDL litigation. Requests such as these thus do not comply with

² These and the other examples that follow throughout these objections are intended to illustrate Centennial's objections and do not constitute an exhaustive list of the objectionable requests.

FRCP 26(b)(1). Accordingly, Centennial requests that this Court modify the Subpoena so as to limit Plaintiffs' requests to documents that are directly relevant to the claims at issue in the MDL litigation.

2. Centennial objects to the Subpoena to the extent it purports to impose burdens other than or beyond those imposed by this Court's Order on Central Enforcement of Subpoenas, dated June 21, 2013 ("Central Enforcement Order") and the Order Granting Plaintiffs Leave to Serve Subpoenas and Qualified Protective Order Regarding Protection of Health Information, dated June 21, 2013 ("Protective Order") (together the "Orders"). The Protective Order limited the information to be provided and timeframe for Plaintiffs' Subpoena to under two years, stating:

The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January 2011 – November 2012 the patients' last known address, the records identifying that NECC was the supplier of the solution, medications or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing, and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.

To the extent the Subpoena seeks documents from before January 2011 and concerning subject matters outside the scope of the Court's Order – including for example documents concerning Centennial's insurance policies, compliance procedures, and communications with regulators – it is out of compliance with the Protective Order. Additionally, the Subpoena gives Centennial only 20 days to respond, and thus violates the Protective Order's mandate granting parties 30 days to produce responsive information. The Subpoena's response date of July 15, 2013 is also abusive as it is three days *before* this

Court will hear objections in accordance with the Central Enforcement Order.

Centennial therefore requests that this Court modify the Subpoena to limit Plaintiffs' requests solely to the subject matter and time constraints specifically enumerated in the Orders.

3. Centennial objects to the Subpoena to the extent it purports to impose burdens other than or beyond those imposed by the Federal Rules of Civil Procedure ("FRCP") and the Local Civil Rules of the United States District Court of Massachusetts ("Local Rules"). As noted above, none of Centennial's patients are parties to any of the MDL litigations, and none have filed suit against Centennial in any forum in relation to NECC medications. Therefore, Centennial does not have any documents germane to resolving any of the claims at issue in the MDL litigation. Rather than tailor their requests to avoid placing an undue burden on Centennial, Plaintiffs demand broad categories of documents that would be burdensome and expensive for Centennial to locate and produce. For example, Plaintiffs seek "any and all documents showing the names of physicians and/or pharmacists that prescribed and/or dispensed NECC products to patients." In order to identify the physicians who prescribed or administered NECC products to patients, Centennial would have to manually review all of the charts of patients who received any medications that the hospital may have purchased from NECC to see which physician prescribed which medication. This would be a labor intensive and expensive undertaking. Similarly, the Subpoena calls for documents and information about Centennial's relationships with other pharmacies and drug manufacturers spanning a five-year period. Those vendors are not parties to the MDL actions nor have they been

linked to the fungal meningitis outbreak in anyway. Accordingly, these requests and others like them are overly broad and unduly burdensome and do not comport with FRCP 45(c)(1). Centennial requests that the Court modify the Subpoena to limit Plaintiffs' requests to documents and information that are relevant to the claims at issue in the MDL litigation, namely documents and information relating to NECC medications provided to Centennial that were the subject of the September and October 2012 recalls. In addition, Centennial requests that the Court order Plaintiffs to reimburse Centennial under FRCP 45(c)(1) for costs and fees it incurs in connection with all proceedings related to the Subpoena.

4. Centennial objects to the Subpoena as overbroad under FRCP 45(c)(1) to the extent no time limitation is included in the requests or to the extent that the time limitations included are unreasonable. Centennial request that the Court modify the Subpoena to limit Plaintiffs' requests to documents and information created between January 1, 2011 and November 30, 2012.

5. Centennial objects to the Subpoena to the extent it calls for disclosure of information or documents protected by the attorney-client privilege, work product doctrine, doctor-patient privilege, or any other applicable privileges ("privileged documents") on the ground that such discovery is impermissible under Rule 26(b) of the FRCP. Centennial requests that the Court modifies the Subpoena so as to limit Plaintiffs' requests to non-privileged documents. In addition, Centennial requests the right to demand the return of any documents that inadvertently may be produced during

discovery if it determines, in its sole discretion, that such documents may contain privileged information.

6. Centennial objects to the Subpoena to the extent it calls for production of documents outside of Centennial's possession, custody, control, in Plaintiffs' possession, custody or control, readily available to Plaintiffs, or attainable by Plaintiffs from public sources, including but not limited to the Food & Drug Administration, Centers for Disease Control, or other federal, state or local government agencies. For example, the Subpoena seeks documents pertaining to NECC sales materials and sales agents. Plaintiffs can and should obtain any information concerning NECC's sales force or NECC's marketing materials from NECC, which is the central party to this litigation. Such requests are overly broad, unduly burdensome, and in excess of FRCP 45. Centennial requests that the Court modify the Subpoena so as to limit Plaintiffs' requests to documents solely within Centennial's exclusive custody and control.

7. Centennial objects to the Subpoena to the extent it calls for disclosure of confidential protected health information protected under the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d et seq. (HIPAA) and regulations promulgated thereunder or the Health Information Technology for Economic and Clinical Health (HITECH) Act, 42 U.S.C. 1176a et seq. and regulations promulgated thereunder which are not covered by the Protective Order. The Protective Order covers only protected health information for patients who received NECC medications from October 2011 through November 2012. Yet, several of the Subpoena's requests would require Centennial to produce information and documents relating to patients who did not receive

NECC medications. In addition, the Subpoena calls for specific patient information and medical records for patients who received NECC medications for four years prior to October 2011. If Centennial produced such information, it would be outside the protection of the Protective Order and would violate its patients' Privacy Rights under HIPAA and HITECH. Centennial requests that the Court modify the Subpoena to require Centennial only to produce information protected under the Protective Order, specifically to provide the names and other information for patients who Centennial can confirm received NECC medications between January 1, 2011 and November 30, 2012.

8. Centennial objects to the Subpoena to the extent it calls for the disclosure of confidential or proprietary business information. For example, the Subpoena calls for documents relating to Centennial's compliance policies and procedures and vendor selection processes. See e.g., Subpoena Ex. B Request Nos. 17-20. These requests would call for Centennial to produce publicly information relating to its internal business practices. Given that Centennial is not a party to the MDL and many of the documents Plaintiffs seek are wholly irrelevant, Centennial should not be forced to disclose this sensitive business information. Centennial requests that the Court modify the Subpoena so as to limit Plaintiffs' requests to non-confidential documents. To the extent that Plaintiffs seek information to authenticate documents to use as exhibits during trial, Centennial will provide Plaintiffs with a business records affidavit to aid Plaintiffs in so doing.

Objections to the Request for Deposition Testimony

Centennial objects to portions of Exhibit A to the Subpoena compelling depositions by corporate representatives on certain designated subjects.

9. Centennial objects to the portions of the Subpoena that seek testimony on topics that are neither relevant to the issues raised in this action nor are reasonably calculated to lead to the discovery of evidence admissible in this action. As noted above, none of Centennial's patients have been infected with fungal meningitis in connection with the administration of NECC medications. Plaintiffs have not pointed to a single Centennial patient who has filed a claim or joined the MDL litigation, and as far as Centennial is aware, none of its patients have even filed suit in connection with the fungal meningitis outbreak in any forum. Consequently, little of the information which Plaintiffs seek is relevant to the claims of any parties in the MDL litigations and Plaintiffs' broad requests are not reasonably calculated to lead to the discovery of such evidence. Moreover, in several cases, Plaintiffs seek to adduce testimony on topics that do not relate to NECC or the fungal meningitis outbreak at all. For example, Plaintiffs command Centennial to produce someone competent to testify regarding its compliance with Tenn. Comp. R. & Regs. R §1140-01-.08, which govern applications for licenses to operate pharmacy practice sites, manufacturers, and wholesalers. Centennial's competence to operate a pharmacy site is not at all relevant to any of the claims at issue in the MDL litigation. Requests such as these thus do not comply with FRCP 26(b)(1). Accordingly, Centennial requests that this Court modify the Subpoena so as to

limit Plaintiffs' requests for testimony to information that is directly relevant to the claims at issue in the MDL litigation.

10. Centennial objects to the Subpoena to the extent it calls for testimony relating to the existence, storage, retrieval, location, and authenticity of irrelevant or otherwise impermissible documents that Plaintiffs' seek in violation with FRCP 26(b)(1). See e.g., Subpoena Ex. A. Request Nos. 1-10. Where the Court modifies or limits Plaintiffs' requests for documents, Centennial requests that it also modify and limit Plaintiffs' corresponding requests for testimony related to those documents.

11. Centennial objects to the Subpoena to the extent it purports to impose burdens other than or beyond those imposed by this Court's Order on Central Enforcement of Subpoenas, dated June 21, 2013 and the Order Granting Plaintiffs Leave to Serve Subpoenas and Qualified Protective Order Regarding Protection of Health Information, dated June 21, 2013 ("Protective Order"). The Protective Order limited the information to be provided and timeframe for Plaintiffs' Subpoena to under two years, stating:

The information requested and produced shall be limited to the names of patients that have been identified as receiving NECC solutions, medications or compounds from January 2011 – November 2012 the patients' last known address, the records identifying that NECC was the supplier of the solution, medications or compound, including lot number, the hospital or healthcare facilities' NECC product purchase records, including order forms, prescriptions, billing, and accounts receivable, the hospital or healthcare facilities' NECC product storage and patient distribution records, and any other information that lead counsel and the PSC reasonably determine necessary to the prosecution and resolution of these actions.

To the extent the Subpoena seeks testimony relating to events or information from before January 2011 and for subject matters outside the scope of the Court's Order, such as

regarding Centennial's insurance policies, compliance procedures, and communications with regulators, it is out of compliance with the Protective Order. See, e.g., Subpoena Ex. A. Request Nos. 22, 28, 30 – 31. Additionally, the Subpoena gives Centennial only 20 days to produce a corporate witness to provide deposition testimony, and thus violates the Protective Order's mandate granting parties 30 days to produce responsive information.³ Centennial therefore requests that this Court modify the Subpoena to limit the testimony sought solely to the subject matter and time constraints specifically enumerated in the Protective Order.

12. Centennial objects to the Subpoena to the extent it purports to impose burdens other than or beyond those imposed by the Federal Rules of Civil Procedure ("FRCP") and the Local Civil Rules of the United States District Court of Massachusetts ("Local Rules"). For the reasons stated above, Centennial does not have substantial information pertinent to the claims at issue in the MDL litigation. Nevertheless, Plaintiffs ignore their obligation to avoid placing an undue burden on Centennial and seek immaterial information that is difficult for Centennial to obtain. Accordingly, such requests are overly broad and unduly burdensome and do not comport with FRCP 45(c)(1). Centennial requests that the Court modify the Subpoena to limit Plaintiffs'

³ Pursuant to the parties' agreement, the proposed deadline of July 15, 2012 for the deposition of a Centennial representative has been adjourned. Subject to the objections set forth herein, Centennial will produce a witness to testify about documents produced in response to this Subpoena at a time and place mutually agreed upon by the parties' counsel, but requests that date be set no sooner than at least 30 days from the time of the Court's ruling on these Objections.

requests for testimony to information relevant to the claims at issue in the MDL litigation, namely information relating to NECC medications provided to Centennial that were the subject of the September and October 2012 recalls. In addition, Centennial requests that the Court order Plaintiffs to reimburse Centennial for its costs and fees for all proceedings related to the Subpoena under FRCP 45(c)(1).

13. Centennial objects to the Subpoena as overbroad under FRCP 45(c)(1) to the extent no time limitation is included in the requests or to the extent that the time limitations included are unreasonable. Centennial requests that the Court modify the Subpoena to limit Plaintiffs' requests for testimony to information relating to events that took place between January 1, 2011 and November 30, 2012.

14. Centennial objects to the Subpoena to the extent it calls for disclosure of information protected by the attorney-client privilege, work product doctrine, doctor-patient privilege, or any other applicable privileges ("privileged documents") on the ground that such discovery is impermissible under Rule 26(b) of the FRCP. Centennial requests that the Court modify the Subpoena so as to limit its requests for testimony to non-privileged information.

15. Centennial objects to the Subpoena to the extent it calls for testimony concerning information in Plaintiffs' possession, custody or control, or that is readily available to Plaintiffs, or attainable by Plaintiffs from public sources. For example, the Subpoena seeks testimony concerning NECC sales materials and sales agents. See e.g., Subpoena Ex. A Request No. 23. Plaintiffs can and should obtain any information concerning NECC sales force or marketing materials from NECC, which is a party to this

litigation. Such requests are overly broad, unduly burdensome, and in excess of FRCP 45. Centennial requests that the Court modify the Subpoena so as to limit Plaintiffs' requests for testimony to information solely within Centennial's exclusive custody and control.

16. Centennial objects to the Subpoena to the extent it calls for disclosure of confidential protected health information protected under the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d *et seq.* (HIPAA) and regulations promulgated thereunder or the Health Information Technology for Economic and Clinical Health (HITECH) Act, 42 U.S.C. 1176a *et seq.* and regulations promulgated thereunder not covered by the Protective Order. For example, the Protective Order covers only protected health information for patients who received NECC medications from October 2011 through November 2012. Several of the Subpoena's requests would require testimony concerning patients who did not receive NECC medications, such as those who received injectable steroids compounded by other pharmacies. See e.g., Subpoena Ex. A Request No. 12. If Centennial provides such information, it would be outside the protection of the Protective Order and would violate its patients' Privacy Rights under HIPAA. Centennial requests that the Court modify the Subpoena limit its requests for testimony to information explicitly protected under the Protective Order, specifically to provide the names and other information of patients who Centennial can confirm received NECC medications between November 2011 and November 2012.

17. Centennial objects to the Subpoena to the extent it calls for the disclosure of confidential or proprietary business information. For example, the Subpoena calls for

testimony about Centennial's compliance policies and procedures, vendor selection processes, document retention policies, and electronic patient medical records systems. See e.g., Subpoena Ex. A Request Nos. 1-10. These requests would call for Centennial to testify publicly about information relating to its internal business processes. Given that Centennial is not a party to the MDL, much of the information that Plaintiffs seek is irrelevant to the claims in the MDL litigation, Centennial should not be forced to disclose this sensitive business information. Centennial requests that the Court modify the Subpoena so as to limit Plaintiffs' requests for testimony to non-confidential information. To the extent that Plaintiffs seek information to authenticate documents to use as exhibits during trial, Centennial will provide Plaintiffs with a business records affidavit to aid Plaintiffs in so doing for relevant documents Centennial produces, if any exist.

18. Centennial objects to the Subpoena because Plaintiffs failed to provide Centennial with the \$40.00 witness fee for attendance at a deposition required upon service of the Subpoena under FRCP 45(b)(1).

For all of the above reasons, nonparty Centennial Medical Center respectfully requests that the Court modify the Subpoena in accordance with the above stated objections.

Respectfully submitted,

/s/ Mark Goodman

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CERTIFICATE OF SERVICE

I, Cari A. Wint, hereby certify that this document, filed through the ECF system, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on July 9, 2013.

/s/ Cari A. Wint
Cari A. Wint